

DATE: December 10, 1971

To : Members of the Faculty, Deans, Department Chairmen and Principal University Officers

FROM : Committee on the Use of Human Subjects in Research, Robert R. Sears, Chairman

SUBJECT: Review Procedure for Use of Human Subjects in Research

New requirements by the U. S. Department of Health, Education and Welfare have necessitated a reorganization of the University's procedures for protecting the rights and welfare of human subjects who participate in research. In the past, separate agencies within DHEW have monitored this problem according to their own guidelines. That Agency has now established a single set of requirements with respect to all DHEW-funded research projects that involve human subjects, and requires a certificate of "institutional assurance" from the University that these protective rules will be met. Since DHEW states that its rules must guide all research done in an institution, regardless of source of funding, it is clear that in the future all plans for research involving the participation of human subjects, in both medical and behavioral sciences, must be evaluated by an appropriate institutional committee.

To provide the necessary mechanism for such evaluation, the Provost has established a University-wide Committee on the Use of Human Subjects in Research. It is composed of two sub-committees. One, for evaluating medical research, is chaired by Professor John Wilson of the Department of Surgery. That sub-committee's jurisdiction is not limited to the Medical School, but will include the reviewing of proposals for medical research with human subjects arising from any part of the university. The second sub-committee, chaired by Professor Robert Sears of Psychology, will be responsible for reviewing all proposals, also without regard to school or department of origin, concerned with non-medical research involving human subjects.

There appears to be no need for any change in the procedures which have been used in the past by the medical sub-committee. This memo is addressed in the main to behavioral scientists within the university, for the major change in the new DHEW policy affects them more significantly. All DHEW agencies will now require that non-medical grants and contract proposals be approved by the single university sub-committee on behavioral science.

What must be submitted. A form for describing any research project that proposes to use human subjects is available from research administration and from most school and departmental administrative offices. It is to be filled in by typewriter and submitted, in the case of behavioral science projects, to Mr. Robert D. Simmons, Research Administration, Encina Hall, in advance of undertaking the research. Medical projects should be described on the appropriate form and forwarded to Mr. H. Jack Geiken, Medical Center E 328. This necessity applies to all such research, regardless of the source of funding or even whether it is sponsored research at all. This

12/10/71

applies to student research as well as that of the faculty and administration.

What is important. The stated purpose of the evaluation procedure is to protect the welfare of human subjects. This includes protection against undue or unnecessary invasion of privacy, disrespect for human dignity, and physical, psychological or social harm. There are many routine research procedures which threaten none of these, and such proposals constitute a necessary but relatively unimportant part of the committee's work-load.

Our major concern is with research which, in DHEW language, places a subject at "risk". There are three general classes of risk. Physical risk is probably not frequent in behavioral science research. Unusual physical activity required of a subject, or the imposition of strong aversive stimulation, or engaging him in a social situation that could involve violence, might endanger his physical well-being. It is important that an investigator foresee possibilities of physical danger and bring them to the attention of the committee on the application form. If necessary, such proposals will be referred to the medical sub-committee for its evaluation.

Psychological risks are far more pervasive among behavioral science researchers. The right to privacy is considered relatively inalienable, and hence invasion of a subject's privacy is, ipso facto, held to be a "risk". Carelessness about the maintenance of confidentiality of protocols could increase the risk. Any procedure that may conceivably produce humiliation, embarrassment, loss of self-esteem, feelings of failure or frustration, feelings of anger toward the experimenter or others, or even acute boredom can be considered undesirable outcomes of the research experience; hence, such procedures must be considered as placing the subject at risk. Any personality change, or change in the subject's feelings or motivation that extend beyond a debriefing period, must also be considered undesirable; possibility of their occurrence constitutes risk. A subject's personal stimulus value to his fellows, such as would be represented by the term "his reputation", is something of value to him, and the possibility of its being damaged constitutes a risk also.

Social risks are related in the main to procedures that may place the reputation or status of a social group or an institution in jeopardy. Procedures designed to measure the characteristics of easily defined sub-groups of a culture may entail risk if the qualities measured are ones which have positive or negative value in the eyes of the group. Even when research does not impinge directly on it, a group may be derogated or its reputation injured. Likewise, an institution, such as a church, a

12/10/71

university, or a prison, must be guarded against derogation, for many people may be affiliated with, or employed by, the institution, and pejorative information about it would injure their reputations and self-esteem. In evaluating social risk, an investigator should ask himself how the findings will appear to persons belonging to any identifiable group -- or affiliated with an institution -- studied and reported upon. These cautions are as equally warranted in the case of anthropological field research in distant cultures as in studies performed in domestic settings.

Informed consent. The key principle in the relationship between a researcher and the people whom he studies is the informed consent of the latter. A subject should be performing a purely voluntary act when he participates. He must have the opportunity to agree or to refuse after he has a full and clear understanding of what will be expected of him in the research process and what its consequences to him will be. He must give his consent without undue pressures being placed upon him, either by offered rewards or implied threats. He must have the option to discontinue his participation at any time without suffering disadvantage.

It is not the intent of the guidelines to prohibit research which carries risk. Many procedures carry only a minimal amount, and if a subject fully understands what the risks are, and gives his consent to collaborate, there can be no objection to the procedure. More serious risks, of course, must be given greater consideration. A fully informed subject may well decide that even a somewhat severe risk is of such potential benefit to science and humanity that he is willing to take it. Furthermore, what may seem a significant risk to some potential subjects may seem minimal to others. In general, the more serious the risk, the more thoughtfully an investigator should try to anticipate the potential benefits of the research. He should ask for participation and consent of subjects only if in his opinion the beneficial outcomes of the research outweigh the risks to which he is subjecting them. The committee will find of particular value a frank discussion of these problems in the application forms.

Minors. Consent for minors or other persons unable to give consent (for legal or other reasons) must be obtained from a legally appropriate guardian. Where a research project enters into the integral activities of a school or other institution, the appropriate consent may be obtained from an administrative officer of the institution. If the research is an independent study unrelated to the specific functions of the institution, however, individual consents should be obtained from parents or other guardians. Blanket consent

12/10/71

for a rather generally described research program is acceptable provided that parents are kept informed of the various procedures being used. They are thus given the opportunity to withdraw their child from the research at any time they may choose. Researchers who work with children or other persons for whom consent must be obtained from a guardian must keep a special principle in mind: a child may not have full power to affirm consent, but regardless of consent obtained from the guardian, the child always retains the power of refusal and the right to discontinue participation at any time.

Informed consent must be obtained from every human subject. In the case of research for which no risks can be identified, the consent may be orally given, or better, indicated by a signature on a sign-up sheet which, at the top, contains a brief description of the experiment. If any risk can be identified, informed consent must be obtained in written form. A copy of the form to be used must accompany the application for review. Such a consent form may contain either a written statement describing the research procedure, or a statement that a standard form of information about the experiment has been presented orally to the subject. In the latter case, the Committee will expect an investigator to provide it with a statement of exactly what he will tell the subjects. All consent forms are to be filed by the researcher and held available for audit for a three-year period.

Deception creates a particularly difficult problem in behavioral science research. Some experiments cannot be done if the subject is fully informed of the procedures and the reasons for them. In most instances the use of deception does lead to risks. Deception like the invasion of privacy, is to be considered ipso facto a producer of "risk". Every effort should be made to avoid its use in the research design.

When deception must be used, however, special emphasis should be laid on clarifying for the subject what consequences he may expect from participating. Whether or not there are discomfiting outcomes, as in the arousal of annoyance, for example, a full explanation of the procedure which was followed is to be given the subject in a debriefing session at the close of the research experience. In presenting his research plans to this Committee, an investigator will be expected to deal fully with both the consent and debriefing aspects of his plan, and to explain clearly why, and to what degree, deception will occur.

Further information. The DHEW guidelines are available from Mr. Robert D. Simmons in Research Administration, and any member of the Committee on the Use of Human Subjects will be glad to discuss with investigators any problems of interpretation. The details as to what information is needed by the Committee for its evaluation are given on the Application sheet, which is available from Mr. Simmons or the Department Offices.